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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,894	12/30/2003	Lynetta J. Freeman	END5094.0515519	7421

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EXAMINER	
VANIK, DAVID L	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,894	FREEMAN ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) *20-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-37* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the applicant's Oath or Declaration filed on 12/30/2003. Receipt is also acknowledged of the applicant's Drawings filed on 12/30/2003.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-19, drawn to a product, a soft tissue implant material, classified in class 424, subclass 422.

   II. Claims 20-37, drawn to a method of filing and closing soft tissue cavities, classified in class 604, subclass 890.1.

The inventions are distinct, each from the other because of the following reasons:

2. Invention I and Invention II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different method. The product as claimed can be used as a drug delivery matrix (See US 5,807,581) or a drug-free biodegradable 3D porous scaffold (See US 2004/0121943).

3. Searching the inventions of Groups I – II together would impose a search burden on the examiner. In the instant case, the search of an collagen-glycosaminoglycan composite and a method of using said composite would impose a search burden on the examiner.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and the search required for each subset of Groups I – II are not required for one another, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. During a telephone conversation with Stephen Albany on 8/8/2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-19. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the specification discloses that the matrix material may comprise at least one layer (paragraph 0034) or multiple layers (paragraph), the instant specification does not specifically disclose a composition comprising between 2 and 8 layers.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,880,429 ('429).

'429 disclose prosthetic meniscus-based compositions comprising between 65% to 98% by dry weight of collagen and 1% to about 25% by dry weight of glycosaminoglycan (abstract). According to '429, the collagen and glycosaminoglycan are linked together and form a porous matrix wherein the pore sizes are in the range of 10-50 microns (Claim 1). The glycosaminoglycan molecules present in the invention advanced by '429 can comprise chondroitin-6-sulfate (Claim 2 and column 3, lines 7-13). The matrix can also comprise a synthetic material, a mesh member (Claim 12 and column 4, lines 60-67).

It is the examiner's position that, inherently, the composition advanced by '429 comprises about 40-60% of pores and self expands to conform to the tissue void when in contact with body fluid. Since the essential elements of the '429 composition are identical to the instant compositions (that is, a cross-linked complex comprising collagen and more than 0.5% of glycosaminoglycan wherein the complex comprises pores or interstices), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '429 anticipates the compositions enumerated in the instant claim set.

The claims are therefore anticipated by US 4,880,429 ('429).

Claims 1, 8-9 ,12-13, 14-15 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,520,916 ('916).

'916 disclose biomaterials comprising a glycosaminoglycan, such as hyaluronic acid, in combination with another polymer, such as collagen (Claim 1 and abstract). The biomaterials can further be impregnated with bioactive substances such as proteins and antibiotics and may form a gel (Claim 3 and column 4, lines 11-18). As seen in figure 2, the matrix comprises interstices.

It is the examiner's position that, inherently, the composition advanced by '916 comprises about 40-60% of pores and self expands to conform to the tissue void when in contact with body fluid. Since the essential elements of the '916 composition are identical to the instant compositions (that is, a cross-linked complex comprising collagen and glycosaminoglycan wherein the complex comprises pores or interstices), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '916 anticipates the compositions enumerated in the instant claim set.

The claims are therefore anticipated US 5,520,916 ('916).

Claims 1-3, 8-16 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,807,581 ('581).

'581 disclose a collagen-based cross-linking composition (abstract). In the composition advanced by '581, collagen may be cross-linked with between 0.1% to 15% of a flexible chain polymer, such as a glycosaminoglycan (column 7, line 55 – column 8, line 67 and column 11, lines 25-32). The collagen-based composition is porous and comprises pores that are between 3 to 30 nanometers in average diameter (column 9, lines 50-62). The composition may further comprise a drug, such as a growth factor (column 10, lines 5-11).

It is the examiner's position that, inherently, the composition advanced by '581 comprises about 40-60% of pores and self expands to conform to the tissue void when in contact with body fluid. Since the essential elements of the '581 composition are identical to the instant compositions (that is, a cross-linked complex comprising collagen and glycosaminoglycan wherein the complex comprises pores or interstices), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '581 anticipates the compositions enumerated in the instant claim set.

The claims are therefore anticipated US 5,807,581 ('581).

Claims 1-3, 8-9, 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,280,954 ('954).

'954 disclose composite materials comprising a covalently linked collagen/ glycosaminoglycan complex (column 2, lines 36-47). Suitable forms of glycosaminoglycan include chondroitin-6-sulfate (column 2, lines 36-47). The collagen/ glycosaminoglycan complex may further comprise a hydrogel (column 11, line 40).

It is the examiner's position that, inherently, the composition advanced by '954 comprises about 40-60% of pores and self expands to conform to the tissue void when in contact with body fluid. Since the essential elements of the '954 composition are identical to the instant compositions (that is, a cross-linked complex comprising collagen and glycosaminoglycan wherein the complex comprises pores or interstices), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '954 anticipates the compositions enumerated in the instant claim set.

The claims are therefore anticipated US US 4,280,954 ('954).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over 4,880,429 ('429) in view of 5,470,911 ('911).

The teachings of '429 are discussed above. '429 does not teach a composition comprising growth factor.

'911 teach a glycosaminoglycan-based composition (abstract). The composition may further be covalently bound to collagen (column 4, lines 26-31). According to '911, it is advantageous to include a growth factor in a composition comprising a covalently linked collagen/glycosaminoglycan complex because growth factors, such as EGF, can be used in the treatment of wounds and can facilitate the regrowth of an implant into normal tissue (column 12, line 44 – column 13, line 3). Because growth factor can advantageously aid in the treatment of wounds and facilitate the regrowth of an implant into normal tissue, one of ordinary skill in the art would have been motivated to add

growth hormone to the prosthetic meniscus-based compositions advanced by '429 . Based on the teachings of '911, there is a reasonable expectation that growth factor would effectively facilitate both wound treatment and the regrowth of an implant into normal tissue. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate growth factor into the prosthetic meniscus-based composition advanced by '429 in view of the teachings of '911.

Claims 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over 4,880,429 ('429) in view of US 2003/0199887 ('887).

The teachings of '429 are discussed above. '429 does not teach a composition comprising a radio-opaque material.

'887 teach a porous embolization device comprising a radio-opaque material (abstract and paragraph 0035). According to '887, it is advantageous to incorporate a radio-opaque material in a surgical composition because said radio-opaque material enables a surgeon to precisely position the device. (paragraph 0035). Because the presence of a radio-opaque material, such as the one enumerated in '887, in a medical device can advantageously enable a surgeon to precisely position said device, one of ordinary skill in the art would have been motivated to add a radio-opaque material to the prosthetic meniscus-based composition advanced by '429 . Based on the teachings of '887, there is a reasonable expectation that a radio-opaque material would effectively

enable a surgeon to precisely position a medical device of composition during a surgical procedure. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a radio-opaque material into the prosthetic meniscus-based composition advanced by '429 in view of the teachings of '887.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

8/11/05

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